



PATENT  
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P.2.

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: )

Jacques MALLET *et al.* )

Serial No. 09/578,453 )

Filed: May 26, 2000 )

For: Pharmaceutical Compositions )  
and Utilization Thereof )  
Particularly for the Treatment of )  
Neurodegenerative Disorders )

Group Art Unit: 1632

Prior Examiner: J. Martin

**Assistant Commissioner for Patents  
Washington, D.C. 20231**

Sir:

**SUBMISSION OF INFORMATION UNDER 37 C.F.R. § 1.56**

To comply with its duty of candor and good faith under 37 C.F.R. § 1.56, and in the spirit of cooperating with the U.S. Patent and Trademark Office (hereafter, "the Office" or "PTO"), applicants and their assignee, Rhône-Poulenc Rorer S.A. ("RPR"), hereby voluntarily disclose to the Office information concerning the conduct of certain present and former employees of the assignee<sup>1</sup> in prosecuting this patent before the United States Patent and Trademark Office.

<sup>1</sup> The employees actually worked for the assignee's U.S. affiliate, Rhône-Poulenc Rorer, Inc. In this submission, RPR refers to either RPR S.A. or RPR, Inc. RPR is presently doing business as Aventis Pharmaceuticals Inc.

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The conduct at issue concerns a practice in RPR's U.S. Patent Department, since terminated, wherein a former PTO patent examiner, who was at the time registered to practice before the Office, assisted in prosecuting matters that may have been within the scope of his 37 C.F.R. § 10.10(b) undertaking.

In light of the possibility that this conduct could be deemed to violate a PTO regulation, RPR hired Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. ("FHF GD"), to conduct a factual investigation. A report detailing the results of that investigation (entitled "Factual Report of an Independent Investigation Conducted on Behalf of Rhône-Poulenc Rorer, Inc.", hereafter, "Report"), and its supporting exhibits,<sup>2</sup> have been submitted to the PTO in U.S. Reissue Application Serial No. 09/538,857, and are hereby incorporated by reference into this submission. A copy of the Report and its supporting exhibits were also filed with the Office of Enrollment and Discipline on October 4, 1999.

### INTRODUCTION

The relevant conduct relates to an RPR employee, R. Keith Baker, Ph.D. ("Baker"), as well as certain colleagues with whom Baker worked in RPR's Patent Department, who were involved in the prosecution of this application. Prior to working

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<sup>2</sup> The materials relied upon in this submission, or the relevant portions thereof, are present in the Report and supporting exhibits, which are designated throughout this paper as "Report, page \_\_\_\_" and "Exh. \_\_, page \_\_, P \_\_," where P1, for example, refers to paragraph 1.

for RPR, Baker was employed as a patent examiner in the PTO for five years, until he resigned on October 28, 1994. Three days after his resignation from the PTO, Baker began his employment at RPR in Collegeville, Pennsylvania.

Under PTO regulations, a former patent examiner (who is registered to practice before the PTO) may not practice before the Office unless he or she signs a written undertaking not to prepare, prosecute or "assist in any manner in the preparation or prosecution" of any patent application disclosing subject matter in his area of responsibility at the PTO. 37 C.F.R. § 10.10(b). Patent examiners sign such an undertaking when they resign from the PTO. This undertaking applies to patent applications filed prior to and within two years from the date the examiner resigns from the Office.

Since he signed such an undertaking,<sup>3</sup> Baker was barred from assisting in the prosecution of certain applications pending at the PTO prior to October 28, 1996, and is still barred from assisting in the prosecution of any applications that are the progeny of applications falling within his bar during those two years. Nonetheless, Baker assisted in the prosecution of RPR patent applications that may have fallen within the scope of his undertaking, even though he did not sign papers submitted to, or actually appear before, the Office with respect to such matters. See Report, Part II, Section H.

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<sup>3</sup> See Supplemental Exhibit 28.

Based on information gathered during FHFGD's investigation, applicants believe that the conduct at issue is not material under 37 C.F.R. § 1.56. Even so, applicants and their assignee are disclosing all information to the PTO that they are aware of pertaining to any possible violation of PTO regulations by its employees. Applicants are filing this submission: (1) expressly advising the PTO of the former examiner's activities, stating specifically where his involvement resides in the prosecution of this patent application; (2) advising the PTO what the actual facts are, while making it clear that further examination may be required if any PTO action was based on those activities; and (3) establishing patentability of the claimed subject matter based on the new, factually accurate, record. *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1572 (Fed. Cir. 1983).

Thus, applicants are voluntarily disclosing to the PTO that an RPR patent agent may have violated his PTO undertaking when he assisted "in any manner" in the prosecution of this patent, as well as all other relevant facts. This disclosure is in furtherance of complying with the duty of candor and good faith required by 37 C.F.R. § 1.56 and with any and all disclosure requirements imposed by 37 C.F.R. Part 10.

### **SPECIFIC CONDUCT AT ISSUE IN THIS APPLICATION**

#### **I. Baker's Assistance in the Preparation of Papers Submitted to the PTO**

In an interview with FHFGD attorneys on May 12, 1999, Baker identified the grandparent (08/624,469) and parent (a continued prosecution application) applications

of this case as two that may have fallen within the scope of his undertaking under 37 C.F.R. § 10.10(b). See Exh. 1 and Exh. 14, pages 104-107.

**A. Application Serial No. 08/624,469**

**1. Preliminary Amendment submitted on April 4, 1996**

Baker stated that he wasn't sure whether he drafted a Preliminary Amendment, which was signed by Julie K. Smith, Ph.D., Esq. ("Smith") and submitted to the Office on April 4, 1996. At the time this application and Preliminary Amendment were prepared and filed, Smith had responsibility for final review of all RPR U.S. national stage applications concerning RPR biotechnology-related inventions. Exh. 15, page 18, lines 10-11; page 35, lines 5-9. After Baker arrived at RPR, these cases were split in half between Smith and Baker. In other words, if a Preliminary Amendment was attached to a biotech national stage application (*i.e.*, filed on the same day), either Smith or Baker drafted it. Regardless of who drafted the paper, however, Smith reviewed and signed all Preliminary Amendments, as well as other papers, prepared as part of the initial filing of these cases. Consequently, it was difficult to tell during the FHFGD interviews whether it was Smith or Baker who actually prepared a particular Preliminary Amendment.

As far as Smith was concerned, this procedure for filing biotech national stage cases had nothing to do with Baker's bar, but was in place because she had ultimate responsibility for the amendments and Baker's name was not listed on the power of attorney documents. Exh. 15, page 26, line 22 - page 27, line 19; page 35, line 5 - page

36, line 1; Exh. 13, page 6, P1. Smith was not aware, at any time, that Baker was working on cases within his bar. Exh. 15, page 37, line 21 - page 38, line 20; page 93, line 18 - page 94, line 1.

**2. Response and Amendment Submitted on March 31, 1997,  
and Response Under 37 CFR § 1.116 Submitted on  
December 5, 1997**

Baker stated that he drafted a Response and Amendment, which was signed by Martin F. Savitzky, Esq. ("Savitzky") and submitted on March 31, 1997, and a Response Under 37 CFR § 1.116 submitted on December 7, 1997.<sup>4</sup> Exh. 14, page 106. After seeing a list of cases during an interview with FHFGD in June 1999 (and being told that Baker stated he participated in the prosecution of this case), Savitzky agreed that Baker may have drafted certain papers submitted to the PTO over his signature. Report, page 33-34. According to Savitzky, however, while Baker "assisted" in the preparation of these papers, he did not "participate" in the prosecution of this case. Exh. 17, page 104, line 22 - page 105, line 20. Furthermore, Savitzky believed that the practice at RPR regarding Baker did not violate PTO regulations. *Id.* at page 77, line 2 - page 78, line 14.

**B. Continued Prosecution Application of Serial No. 08/624,469**

According to an internal "Patent/TM File Opening Paper" in RPR's internal

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<sup>4</sup> Baker also stated that he prepared internal RPR correspondence dated October 9, 1997, and January 8, 1998, reporting out Office actions, the latter including commentary on the Office Action, which were signed by Savitsky. Exh. 14, page 105.

prosecution file, this case was docketed to "RG2" (a docketing user ID code for Baker).  
See Report, pages 16-20.

**1. Preliminary Amendment Submitted May 28, 1998**

It is possible that Baker drafted a Preliminary Amendment, which was signed by Paul F. Fehlner, Ph.D., Esq. ("Fehlner"), and submitted with a Continued Prosecution Application (CPA) Request Transmittal on April 15, 1997.<sup>5</sup> Exh. 14, page 106.

**2. Response and Amendment Submitted February 16, 1999**

Baker said that he drafted the Response and Amendment submitted on February 16, 1999, which was signed by Ray S. Parker, Ph.D., Esq. ("Parker").<sup>6</sup> Exh. 14, page 106. Parker declined to be interviewed by FHFGD. See Exh. 24 and Exh. 25. By the time he left the company in April 1999, Parker had become the head of the medicinal chemistry group in RPR's patent department. Exh. 16, page 22, lines 13-14. According to Baker, if Parker signed a substantive PTO paper in this case, Baker was the one who prepared it. Exh. 12, page 3, P1; Exh. 14, page 102. Baker also stated that he had a discussion with Parker at a time just before Parker resigned from RPR. According to Baker (as consistent with the beliefs of Savitzky), Parker apparently said to Baker that

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<sup>5</sup> Upon review of RPR's internal prosecution file, Baker could not tell whether he or Fehlner prepared this Preliminary Amendment, but Baker believed he wrote it.

<sup>6</sup> Baker stated that he prepared internal RPR correspondence dated August 18, 1998, reporting out and providing comments on an Office action dated August 13, 1998, which was signed by Fehlner. Exh. 14, page 107.

he thought the PTO rules would allow Baker to work on cases within his bar, but prevented him from signing PTO papers. Exh. 12, page 4, P2.

### **REMARKS**

Although Baker, as a former examiner, may have violated his undertaking under § 10.10(b) when he assisted "in any manner" in the prosecution of this case, applicants submit that this conduct, as well as the conduct of any other practitioner involved in the prosecution of this case, does not rise to the level of inequitable conduct before the Office under the standards set forth in Rule 56 and the relevant case law. In an abundance of caution, however, applicants submit that the effect of any misconduct is purged by their disclosure of it to the Office via this submission, as well as the Report and exhibits incorporated by reference.

#### **I. The Conduct at Issue Is Not Material**

"Applicants for patents are required to prosecute patent applications in the PTO with candor, good faith, and honesty." *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). Moreover, applicants are required to disclose material information to the PTO. "[A]ffirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with the intent to deceive" constitutes inequitable conduct. *Id.*

An inequitable conduct analysis requires consideration of several issues before a final determination is reached:



1. The tribunal must determine whether the misrepresentation meets a threshold level of materiality;
2. It must also determine whether the evidence shows a threshold level of an intent to mislead the PTO;
3. Once the threshold levels of materiality and intent have been established, the tribunal weighs materiality and intent because the more material the misrepresentation, the less evidence of intent that will be required in order to find that inequitable conduct has occurred; and
4. In light of all of the circumstances, the tribunal must then determine whether the applicant's conduct is so culpable that the patent should be held unenforceable.

*See Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1327 (Fed. Cir. 1998).

The conduct described in this submission does not rise to the level of inequitable conduct because it does not meet the required threshold level of materiality.

Information regarding the relevant conduct would not be important to a reasonable examiner in deciding whether to grant a patent, and the applicants did not gain any unfair advantage in the examining process from Baker's involvement.

The applicants did not benefit from any undue influence on the examiner(s) responsible for this application stemming from any prior relationship with Baker. The investigation unequivocally shows that during the prosecution of this application Baker did not directly interact with the PTO or its employees. As noted above, he never

signed a paper submitted to the Office. Also, during prosecution of this application, he never communicated directly with PTO personnel, either by telephone or in person. See Report, page 49. Baker could not improperly assert influence on the examiner(s) if there was no knowledge of his involvement with the case.

Therefore, even assuming that Baker had an intent to deceive the PTO by shielding his involvement in the prosecution of this patent from the Office, his actions were not material.

**A. The Former Examiner's Conduct Lacks Materiality**

In 1992, the PTO revised Rule 56 to more clearly define the information that applicants are required to disclose to the PTO:

- (b) Under this section, information is **material to patentability** when it is not cumulative to information already of record or being made of record in the application, and,
  - (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
  - (2) It refutes, or is inconsistent with, a position the applicant takes in:
    - (i) Opposing an argument of unpatentability relied on by the Office, or
    - (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56 (1992) (emphasis added).

This is the administrative standard for materiality in effect during the period of time in which the conduct at issue took place. If information is not material to

patentability under this standard, the PTO does not require an applicant to disclose it to the Office.<sup>7</sup> 57 Fed. Reg. 2023 (1992). The conduct described in the Report and herein does not fall within this definition of information "material to patentability" that an applicant must disclose to satisfy the duty of candor.

While the information that a former examiner may have assisted in prosecuting this patent is not cumulative of information already of record, applicants prior failure to disclose this information to the PTO does not violate the duty to disclose information material to patentability. This information does not, either alone or in combination with other information, establish a *prima facie* case of unpatentability of any claim in this patent. In addition, it does not refute, nor is it inconsistent with, any position taken by applicants in opposing an argument of unpatentability or asserting an argument for patentability. The mere fact that a former examiner may have been involved with the patent application does not, *per se*, fall within the definition of materiality provided by 37 C.F.R. § 1.56.

Under the definition of materiality set forth in the former Rule 56 as promulgated from 1977 to 1992, "[i]nformation is 'material' when there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent." Even under this definition of

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<sup>7</sup> See 37 C.F.R. § 1.56(a) ("There is no duty to submit information which is not material to patentability of any existing claim.").

"materiality," however, Baker's actions relating to the prosecution of this patent are not material.

Baker's involvement was simply not germane to patentability issues considered during examination. His involvement in this application did not change the merits of the invention, did not change the merits of the arguments and amendments submitted in support of patentability, and did not affect the ultimate determination of patentability of the claimed invention by the PTO. No confidential information was used in preparing the papers submitted to the PTO. See Report, page 49, n.44. The examiner(s) who received applicants' papers responded to them based on the amendments and/or merits of the arguments therein. Baker's involvement would not have been important to a reasonable examiner in deciding to grant a patent. Consequently, Baker's conduct was not material under the standard of the former Rule 56.

Applicants recognize that while the revised Rule 56 states that submitting all information within the definition of § 1.56(b) will satisfy the duty to disclose information material to patentability, this does not necessarily mean that the broader duty of candor and good faith under § 1.56(a) has been satisfied. 57 Fed. Reg. 2022 (1992); M.P.E.P. § 2001.04 ("The language of 37 CFR 1.56 (and 37 CFR 1.555) has been modified effective March 16, 1992 to emphasize that there is a duty of candor and good faith which is broader than the duty to disclose material information."). In its final rule making in 1992, the PTO stated that amended Rule 56 "does not attempt to define the spectrum of conduct that would lack the candor and good faith in dealing with the Office which is

expected of individuals who are associated with the filing or prosecution of a patent application." 57 Fed. Reg. at 2023.

Even if Baker's actions violate his section 10.10(b) undertaking and the broad duty of candor and good faith imposed by Rule 56, his actions do not constitute inequitable conduct. To constitute inequitable conduct, there must be an affirmative misrepresentation or failure to disclose information that gives the applicant an unfair advantage in the examining process. If the conduct in question does not relate to patentability of the claims or does not provide an applicant with an unfair advantage in the examining process, it is not material, and thus not a basis for sustaining a finding of inequitable conduct.

For example, one unfair advantage in the examining process that an applicant might seek to obtain is the expedited prosecution of a patent application without conducting a thorough search of the prior art. As one basis for being placed at the head of the examining line, an applicant must make a sworn statement that a prior art search has been done. In *General Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1411 (Fed. Cir. 1994) the Court noted:

The whole point of the PTO requirement that a petition to make special include a sworn statement that the applicant has made a *careful and thorough search* is that, in return for an applicant being put at the head of the examination line, he must make an extra effort to *look for* and produce all relevant prior art, in other words, to assist an examiner who is being asked to expedite examination.

*Id.*

The Federal Circuit went on to hold that, as a matter of law, making "a false statement in a petition to make special is material if . . . it succeeds in prompting expedited consideration of the application." *Id.* Thus, a misrepresentation relevant to providing required assistance to the examination process, coupled with an intent to deceive, which procured an unfair advantage that the applicant was not entitled to, was found to be material, and an inequitable conduct defense was sustained.

The importance of a misrepresentation's capacity to bear on patentability or the examination process and to induce an examiner to act, thereby providing an unfair advantage to the applicant, is also evident in *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir.), *cert. denied*, 111 S. Ct., 1548 (1997) (hereafter, "*Eli Lilly*"). In *Eli Lilly*, the trial court ruled that one of the patents in suit was unenforceable for inequitable conduct because the applicants used an uncertified plasmid to hasten their determination of rat insulin-encoding cDNA sequences, and misrepresented in their specification that they had used another, certified plasmid.<sup>8</sup> 119 F.3d at 1569.

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<sup>8</sup> In 1976, NIH issued safety guidelines that governed the conduct of all NIH-supported research in the area of recombinant DNA. These guidelines established controlled conditions for the conduct of experiments involving the production of recombinant DNA molecules and their insertion into organisms, e.g., by plasmids. The safety guidelines mandated that no plasmid could be considered to fall within an approved classification until it had been certified for use by the NIH Recombinant DNA Advisory Committee. *Regents of the University of California v. Eli Lilly and Co.*, 39 U.S.P.Q.2d 1225, 1248-49 (D.C. S.D. Ind. 1995).

On appeal, Eli Lilly argued that the determination of inequitable conduct should be upheld, relying on the holding in *General Electro Music*. *Id.* at 1570. Specifically, Eli Lilly argued that as long as the misrepresentation was made to obtain a patent more quickly than otherwise, then it is sufficient to support a finding of inequitable conduct.<sup>9</sup> *Id.* The Federal Circuit did not agree that *General Electro Music* supported Eli Lilly's argument. The court distinguished its holding in that case, based on the impact the asserted misrepresentation had on the examiner:

In *General Electro Music*, we concluded that "a false statement in a petition to make special is material if, as here, it succeeds in prompting expedited consideration of the patent." We so concluded because, by filing a petition to make special, the applicant "requested special treatment and induced reliance on its statement that a prior art search had been conducted." As explained above, UC's alleged mischaracterization of the pMB9 work as an actual example did not induce the examiner to act, or not to act, in reliance thereon. **UC got no advantage in the patent examining process.** Therefore, we conclude that the district court clearly erred in finding that the misidentification of the plasmid was material to patentability.

*Id.* at 1571; emphasis added.

As was the case in *Eli Lilly*, applicants here received no unfair advantage in the patent examining process. Importantly, there was no opportunity for Baker to exert an undue influence on PTO personnel because he was not directly involved in the

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<sup>9</sup> The U.C. applicants in the *Eli Lilly* case could not have disclosed using the uncertified vector in their application, because this would have violated NIH guidelines governing recombinant DNA experiments. To file their application earlier, Eli Lilly argued, the inventors falsified the identity of the vector in their application. *Id.* at 1570.

prosecution and he was never identified to the PTO with respect to this application.<sup>10</sup> In addition, the documents and recollections of all present and former staff in the RPR Patent Department interviewed by FHFGD support the conclusion that no confidential information obtained from the PTO was used in prosecuting this or any of the other applications at issue. The lack of any evidence of an unfair advantage to RPR obtained from Baker's involvement in this application further supports the conclusion that his conduct does not satisfy the threshold level of materiality.

A finding of inequitable conduct requires that threshold levels of both intent and materiality be established. *Cf. Allen Organ Co. v. Kimball International, Inc.*, 839 F.2d 1556, 1567-68 (Fed. Cir. 1988) ("[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct.") Thus, even if Baker had an intent to shield his participation in this application from the PTO, a *prima facie* case of

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<sup>10</sup> Because Baker was never identified and did not appear before the Office during prosecution of this case, the present situation is clearly distinguishable from the facts of *Kearney & Trecker v. Giddings & Lewis*, 452 F.2d 579 (7<sup>th</sup> Cir. 1971), *cert denied*, 173 U.S.P.Q. 385 (1972) (claims held unenforceable in a patent infringement suit because plaintiff's remedial action did not "cleanse its hands" when an examiner retired from PTO and then worked on reissue of two patents, one of which he had originally allowed). Specifically, in *Kearney & Trecker*, the former PTO examiner: (1) was involved with the prosecution of the patent while at the Office; (2) left the PTO to work for the plaintiff who owned that patent; (3) participated in the prosecution of a reissue application of the patent, as well as the reissue of an acquired prior art patent; and (4) spoke directly to the examiner, a previous subordinate at the PTO, during the reissue proceedings. Furthermore, plaintiff's remedial action to purge the prohibited conduct occurred only after the conduct was uncovered during pretrial discovery in an infringement suit brought by the plaintiff.



inequitable conduct cannot be established because his conduct was not material under any definition in the relevant PTO regulations and case law.

**B. The Conduct of the Other Practitioners Lacks Intent and Materiality**

Baker's conduct is not the only conduct that applicants bring to the Office's attention. The conduct of other registered professionals also may be relevant.

As discussed above, it is possible that four individuals, Smith, Savitsky, Fehlner, and Parker, may have reviewed and signed papers submitted to the PTO, which were prepared by Baker. See "Specific Conduct At Issue In This Application" on pages 5-8 of this paper. Facts uncovered during an independent investigation by FHFGD, however, indicate that these individuals probably never had a clear understanding of Baker's section 10.10(b) undertaking. See Report, page 43. Smith did not know that Baker was working on cases within his bar. Savitzky and Fehlner (and possibly Parker)<sup>11</sup> believed that reviewing and signing of papers prepared by Baker was acceptable conduct. *Id.* at pages 23-25, 30, and 43-45. In other words, they thought that they were abiding by PTO regulations, including section 10.10(b).

"To be guilty of inequitable conduct, an applicant must have intended to deceive the PTO by failing to disclose material information." *Braun Inc. v. Dynamics Corp. of America*, 975 F.2d 815, 822 (Fed. Cir. 1992). "There must be not only a

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<sup>11</sup> As noted above on page 7, FHFGD did not interview Parker (see Exh. 24 and Exh. 25) and cannot speak to his conduct. Anecdotal information, however, suggests that Parker considered the practice to be acceptable in view of Baker's undertaking. Report, page 30.

misrepresentation, but also actual knowledge of falsity . . . ." *Jaskiewicz v. Mossinghoff*, 822 F.2d 1053, 1058 (Fed. Cir. 1987). "[T]he involved conduct, viewed in light of all of the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988); *Jaskiewicz*, 822 F.2d at 1059 (holding that when determining whether a practitioner has violated his duty of candor under Rule 56, "[t]he PTO must look to all the facts and circumstances involving the questionable conduct before finding intentional misconduct"). Applicants submit that the individuals who signed papers for Baker did not act with an intent to mislead the PTO.

Smith and Savitzky never had a firm understanding of Baker's PTO bar, in terms of either the barred subject matter or the contours of the actual undertaking itself. Baker was the first, and only, former patent examiner hired by the assignee. Report, page 40. Although there was a general understanding that Baker was precluded from working on some applications, the details of that proscription were not known by other members of the RPR Patent Department. *Id.* at pages 42-45. Smith and Savitsky never reviewed Baker's letter from OED defining the scope of his undertaking. *Id.* at pages 21 and 25. They believed in good faith that the practice at RPR regarding Baker did not violate PTO regulations.

Although Smith was aware that Baker was not signing papers he prepared for filing in the PTO, she did not know why he did not sign them, nor did she think it was

unusual. Smith was required to sign off on all papers relating to biotech U.S. national stage filings in the PTO, and Baker's name was not listed on the power of attorney documents. Exh. 15, page 26, line 22 - page 27, line 19; Exh. 13, page 6, P1. Smith reviewed and signed preliminary amendments drafted by Baker because Smith had power of attorney and because she had ultimate responsibility for the amendments. Exh. 15, page 35, line 17 - page 36, line 1. Smith was not aware, at any time, that Baker was working on cases within his bar. *Id.* at page 37, line 21 - page 38, line 20; page 93, line 18 - page 94, line 1.

Savitzky believed that as long as Baker's involvement in an application within the scope of his undertaking was shielded from the PTO, thereby preventing any possibility of an undue influence working to RPR's advantage, they were conducting themselves appropriately under, and in compliance with, the rules governing conduct before the PTO. Exh. 17, page 77, line 2 - page 78, line 14.

Fehlner, like Savitzky, believed that as long as Baker's involvement in an application within the scope of his undertaking was shielded from the PTO, thereby preventing any possibility of an undue influence working to RPR's advantage, he was conducting himself appropriately under, and in compliance with, the rules governing conduct before the PTO. Exh. 16, page 41, line 3 - page 42, line 22. Specifically, Fehlner believed it was permissible for Baker to work on the case, as long as it was done under the supervision of someone else who carefully reviewed, signed, and adopted the paper Baker prepared as their own. Exh. 16, page 41, line 22 - page 42,

line 22; page 103, line 6 - page 104, line 21. Hence, Baker was not allowed to make personal contact with his former colleagues at the PTO, or otherwise have an opportunity to directly influence in some unfair way the prosecution or examination of an application. Exh. 16, page 42, lines 11-18.

Accordingly, applicants submit that by reviewing, adopting, and signing papers Baker drafted, Smith, Savitzky, Fehlner (and likely Parker) were not acting with a deliberate intent to deceive the PTO. Perhaps the most telling evidence in support of this conclusion is the fact that they signed the papers at all. If these members of the assignee's Patent Department signed papers drafted by Baker, knowing that by doing so they would be participating in a deception of the PTO, they arguably would have been exposing themselves to the prospect of being disciplined under 37 C.F.R. § 10.23(c)(2)(ii). Although one's own denial of intent to deceive "may not be sufficient to overcome circumstantial evidence of intent to deceive," *Lipman v. Lehman*, 1996 U.S. Dist. LEXIS 10479 (D.D.C. 1996), *aff'd sub nom*, *Lipman v. Dickinson*, 174 F.3d 1363 (Fed. Cir. 1999), the circumstantial evidence here does not indicate that any of the members of RPR's patent department who signed Baker's papers did so with the deliberate intent of deceiving the PTO.

Furthermore, if Baker's actions are not material (for the reasons set forth in the above section), then the conduct of the other members of the department is also not material. Before signing and submitting the papers to the PTO, Baker's drafts were reviewed, typically edited, and adopted by the signers. Report, Part II, Section H. No

confidential information was used in preparing these papers. *Id.* at page 49, n.44.

Thus, a reasonable examiner would have examined the papers as if they had been prepared by the signer. In fact, the PTO examiner(s) responsible for this application responded to these papers based on the amendments and/or merits of the arguments therein.

Since no confidential information was used during prosecution, and applicants received no unfair advantage in the patent examining process, the identity of the drafter of these papers has no bearing on the merits of the arguments. Thus, applicants believe that the examiner(s) would not have decided anything differently regarding the patentability of the claims, regardless of whether Baker or anyone else in the RPR Patent Department drafted the papers. The fact that Baker drafted papers signed by others in the RPR Patent Department, therefore, should not be found material to patentability or material under any definition in the PTO regulations. Accordingly, applicants submit that the conduct does not rise to the level of inequitable conduct. See *Eli Lilly*, 119 F.3d at 1570-71.

## II. APPLICANTS PURGE THE EFFECT OF THIS CONDUCT

As explained above, applicants aver that no inequitable conduct was committed. If the conduct disclosed herein were to rise to the level of inequitable conduct, however, the effect of that conduct may be purged. Therefore, in an abundance of caution, applicants hereby submit all relevant information in this paper, as well as the Report and corresponding exhibits, to affect a "cure" or "purge" of any possible inequitable conduct committed by RPR employees in the prosecution of this case.

The controlling precedent on purging inequitable conduct is *Rohm and Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556 (Fed. Cir. 1983). In *Rohm and Haas*, the Federal Circuit set out three requirements that an applicant must satisfy to cure misconduct before the PTO:

The **first** requirement to be met by an applicant, aware of misrepresentation in the prosecution of his application and desiring to overcome it, is that he expressly advise the PTO of its existence, stating specifically wherein it resides. The **second** requirement is that, if the misrepresentation is of one or more facts, the PTO be advised what the actual facts are, the applicant making it clear that further examination in light thereof may be required if any PTO action has been based on the misrepresentation. **[Third]**, on the basis of the new and factually accurate record, the applicant must establish patentability of the claimed subject matter.

*Rohm and Haas*, 722 F.2d at 1572 (emphasis added). Where an intentional material misrepresentation has been made, a complete cure must be demonstrated by "clear, unequivocal, and convincing evidence." *Id.*

To comply with their duty of candor and fair dealing with the Office, and in

accordance with the Federal Circuit's mandate in *Rohm and Haas*, applicants hereby expressly inform the PTO of the following:

1. A former examiner has assisted in prosecuting this application and that assistance may constitute a violation of his § 10.10(b) undertaking. A detailed description of the relevant conduct, both in general and specifically as it applies to this application, is described in the attached Report and its supporting exhibits. Also, the facts that are relevant to this application appear in the section entitled "Specific Conduct at Issue in this Application" of this paper.

2. The section entitled "Specific Conduct at Issue in this Application" on pages 6-7 sets forth the actual facts, as developed by an independent investigation performed at the assignee's request. This section discloses the most significant instances in which Baker assisted the prosecution of this case. Although no definition of "assisting in any manner" is provided in the regulations, applicants have broadly interpreted it for the purpose of this submission and the Report. Thus, out of caution, all known details of Baker's involvement in the prosecution of this case are presented in the Report and supporting exhibits, which are incorporated by reference.

Applicants are not aware of any PTO actions based on conduct described above. Nonetheless, they request further examination of this application based upon the factually accurate record.

3. Applicants submit that the factually accurate record does not impact on the patentability of the claimed subject matter. The instant facts are unlike a situation

where material prior art was deliberately withheld from the PTO—prior art that might render the claims unpatentable. Neither is it like a situation, as in *Rohm & Haas*, where false data is submitted to the PTO with a deliberate intent to deceive.

As discussed above, Baker did not make use of confidential information, he could not have unduly influenced PTO employees because his actions were not known to the Office, and the amendments and arguments submitted to the PTO have already been evaluated on their merits. When viewed in the context of the factually accurate record, the merits of those arguments do not change. If the Office considered them persuasive before, they should still be so. Thus, applicants submit that the disclosed conduct has no effect on the patentability of the claimed invention.

#### **SUMMARY**

Applicants believe that this submission satisfies their duties of candor and disclosure to the Office as those duties apply to the conduct described above. They respectfully request further examination of the application in light of this disclosure.




MALLET *et al.*  
Serial No.: 09/578,453

Attorney Docket No. 3804.0114-02

Please grant any extensions of time required to enter this paper and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: May 25, 2001